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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

OLSEN, KAJ K

ART UNIT

PAPER NUMBER

1753

DATE MAILED: 01/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/674,695

Applicant(s)

PIERCE ET AL.

Examiner

Kaj K. Olsen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-16 and 18-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-16 and 18-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The examiner has withdrawn the outstanding 112 first and second paragraph rejections of claims 1, 5, 15 and 20 in view of the applicant's amendment to those claims.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 3-5, 8 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Gilmartin (USP 5,795,453).
4. These claims remain rejected over Gilmartin for the reasons set forth in the previous office action. Applicant traverses this rejection on the grounds that Gilmartin includes both the enzyme and the mediator in the conductive track, in contrast to the now claimed enzyme, substrate for the enzyme, or the mediator. First, applicant is not correct about Gilmartin only teaching placing both the mediator and enzyme in the electrode ink. In particular, col. 9, ll. 42-46 discusses how the enzyme can be deposited over the electrode itself. Col. 10, ll. 49-52 discusses how the enzyme is only put into the ink if the enzyme layer (i.e. the layer discussed in col. 9) is not desired. Hence, Gilmartin teaches placing the mediator in the electrode ink without the enzyme itself in contrast to the applicant's suggestion. Second, applicant's use of "having" in claims 1 and 16 is interpreted as being open claim language like that of "comprising". See

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MPEP 2111.03 under the heading "OTHER TRANSITIONAL PHRASES". Hence, claims 1 and 16 need only comprise one of the enzyme, the substrate or the mediator, but could comprise two or even three of the set forth items and still read on the claims. There is nothing in the claims that explicitly restricts the presence of an enzyme or a substrate when a mediator is present, or the presence of a substrate or mediator when an enzyme is present, or the presence of an enzyme or mediator when the substrate is present. Therefore, even if the examiner agreed with the applicant about its interpretation of Gilmartin (i.e. Gilmartin only teaches placing both the enzyme and mediator in the conductive track), Gilmartin would still anticipate the claims when the enzyme and the mediator are both present in the conductive track.

5. Claims 1, 3-16, 18-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Feldman et al (USP 6,299,757). Feldman was previously utilized for a 103 rejection in further view of Gilmartin. Applicant's amendment to the claims now necessitates Feldman anticipating the claims as discussed below.

6. Feldman discloses a biosensor (col. 1, ll. 13-14) having: (a) an electrode support (col. 26, ll. 25-26 and Fig. 2, 38); (b) an arrangement of electrodes disposed on the electrode support, the arrangement of electrodes comprising at least a working electrode and at least a second electrode (col. 26, ll. 22-23 and Fig. 2, 22 and 24); (c) a first conductive track leading from the working electrode to an electrical contact associated with the working electrode and a second conductive track leading from the second electrode to an electrical contact associated with the at least second electrode (Fig. 2, 22 and 24); and (d) at least one reagent incorporated in the working electrode (col. 21, ll. 28-31) comprising an enzyme (col. 24, ll. 18-43) and a mediator (col. 15, ll. 20- col. 24, ll. 15). Specifically, the enzyme can comprise glucose oxidase or glucose

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dehydrogenase (col. 24, ll. 27-28) and the mediator can comprise ferrocene (col. 15, ll. 32), quinones (col. 20, l. 50-col. 21, l. 15), ferricyanide (col. 22, l. 28) or ruthenium bipyridyl complexes (col. 15, ll. 33-38).

7. With respect to the new limitation stating that the component of the conductive track could be a “substrate for an enzyme”, applicant appears to be referring to a substrate that is reactive with the enzyme (p. 13, ll. 20-23). However, the amended claims merely broadly recite the presence of a substrate for an enzyme, which could be any material that could support an enzyme and that that material need not be reactive with the enzyme. To limit the interpretation of the claims based on language from the specification would unduly limit the scope of the applicant’s claims. In view of this interpretation, any number of the materials listing at col. 8, ll. 2-22 would read on the broadly defined “substrate for an enzyme”, giving the claim language its broadest reasonable interpretation, because any of these materials could support an enzyme.

8. With respect to claims 3, 4, 18 and 19, these claims only further limit claims 1 and 16 when mediator or enzyme is selected from the choice of components incorporated into the conductive track. Because claims 3, 4, 18 and 19 do not actually require that enzyme or mediator be chosen from the groupings of claims 1 and 16, claims 3, 4, 18 and 19 do not further limit claims 1 and 16 when the substrate is chosen from claims 1 and 16.

9. With respect to the various other dependent claim limitations, see the discussion of Feldman and these limitations in the previous office action.

10. Claims 1, 3, 4, 10, 12, 13 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Hughes (USP 6,129,823). Hughes was previously utilized for a 103 rejection in further view

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of Gilmartin. Applicant's amendment to the claims now necessitates Hughes anticipating the claims as discussed below.

11. Hughes discloses a biosensor (col. 1, ll. 5-6) having (a) an electrode support (col. 2, l. 10 and Fig. 1, 1); (b) an arrangement of electrodes disposed on the electrode support, the arrangement of electrodes comprising at least a working electrode and at least a second electrode (col. 2, ll. 11-12 and Fig. 1, 4, 5 and 5a); (c) a first conductive track leading from the working electrode to an electrical contact associated with the working electrode and a second conductive track leading from the second electrode to an electrical contact associated with the at least second electrode (Fig. 1, 2), and (d) at least one reagent incorporated in the working electrode (col. 4, ll. 28- 29) comprising an enzyme and a mediator (col. 4, ll. 40-42).

12. With respect to the new limitation stating that the component of the conductive track could be a "substrate for an enzyme", applicant appears to be referring to a substrate that is reactive with the enzyme (p. 13, ll. 20-23). However, the amended claims merely broadly recite the presence of a substrate for an enzyme, which could be any material that could support an enzyme and that that material need not be reactive with the enzyme. To limit the interpretation of the claims based on language from the specification would unduly limit the scope of the applicant's claims. In view of this interpretation, the materials listing at col. 4, ll. 34-35 would read on the broadly defined "substrate for an enzyme", giving the claim language its broadest reasonable interpretation, because any of these materials could support an enzyme.

13. With respect to claims 3 and 4, these claims only further limit claim 1 when mediator or enzyme is selected from the choice of components incorporated into the conductive track. Because claims 3 and 4 do not actually require that enzyme or mediator be chosen from the

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groupings of claim 1, claims 3 and 4 do not further limit claim 1 when the substrate is chosen from claim 1.

14. With respect to the various other dependent claim limitations, see the discussion of Hughes and these limitations in the previous office action.

Claim Rejections - 35 USC § 103

15. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

16. Claims 1, 3-16 and 18-28 in the alternative are rejected under 35 U.S.C. 103(a) as being unpatentable over Feldman and Gilmartin.

17. With respect to these claims, even if the “substrate” of Feldman would interpreted to not read on the newly claimed “substrate” of claims 1 and 16, the claims would still be rendered obvious over the combination of Feldman and Gilmartin as set forth in the previous office action. Applicant’s traversal of this rejection appears to rely on the applicant’s perceived failings of the teaching of Gilmartin with respect to the new claim language. However, the examiner already addressed the issue of this new claim language and Gilmartin in the 102 rejection above. The examiner will not reiterate those arguments here.

18. Claims 1, 3, 4, 10, 12, 13, and 15 in the alternative are rejected under 35 U.S.C. 103(a) as being unpatentable over Hughes and Gilmartin.

19. With respect to these claims, even if the “substrate” of Hughes would interpreted to not read on the newly claimed “substrate” of claims 1 and 16, the claims would still be rendered obvious over the combination of Hughes and Gilmartin as set forth in the previous office action.

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Applicant's traversal of this rejection appears to rely on the applicant's perceived failings of the teaching of Gilmartin with respect to the new claim language. However, the examiner already addressed the issue of this new claim language and Gilmartin in the 102 rejection above. The examiner will not reiterate those arguments here.

Conclusion

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kaj Olsen whose telephone number is (571) 272-1344. The examiner can normally be reached on Monday through Thursday from 5:30 A.M. to 3:00 P.M. and on alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AU 1753
January 5, 2006



KAJ K. OLSEN
PRIMARY EXAMINER